

OPHTHALMIC DEVICES PANEL

One Hundred and Fourth Meeting

OPEN SESSION

AUGUST 1, 2002

8:30 A.M. - 3 P.M.

8:30	Call to Order	Jayne S. Weiss, M.D. - Chair
	Introductory Remarks	Sara M. Thornton - Executive Secretary
	Conflict of Interest Statement	
	Appointment to Temporary Voting Status	

8:45 - 9:15	OPEN PUBLIC HEARING
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OPEN COMMITTEE SESSION

Jayne S. Weiss, M.D., Chair

9:15 - 9:30

DIVISION UPDATE

A. Ralph Rosenthal, M.D., Director
David M. Whipple, Deputy Director
Division of Ophthalmic and Ear, Nose and Throat Devices

BRANCH UPDATES

James F. Saviola, O.D.
Chief, Vitreoretinal and Extraocular Devices Branch
Donna R. Lochner
Chief, Intraocular and Corneal Implants Branch
Everette T. Beers, Ph.D.
Chief, Diagnostic and Surgical Devices Branch

PMA P970043/S010

9:30 - 10:30

SPONSOR PRESENTATION

CustomCornea™ Myopic LASIK
With the LADARVision™4000 System

10:30 - 11:00

Panel Questions for the Sponsor

11:00 - 11:20

FDA PRESENTATION

Everette T. Beers, Ph.D. – Introduction
Jan C. Callaway – Team Leader
Bruce A. Drum, Ph.D. - Physicist
Malvina B. Eydelman, M.D. - Medical Officer

11:20 - 11:30

Panel Questions for FDA

11:30 - 11:35

Additional Comments From the Sponsor

11:35 - 12:35

LUNCH

12:35 - 3:00 p.m.

COMMITTEE DELIBERATIONS

Primary Panel Reviewers:

PANEL DISCUSSION OF P870043/S010
to include FDA questions to the Panel

30-MINUTE OPEN PUBLIC HEARING SESSION

FDA – CLOSING COMMENTS (5 minutes)

SPONSOR – CLOSING COMMENTS (5 minutes)

Voting Options Read

PANEL RECOMMENDATION TAKEN BY VOTE

POLLING OF PANEL VOTES

COMMENTS FROM CONSUMER AND INDUSTRY REPRESENTATIVES

FINAL PANEL COMMENTS

3:00 p.m.

OPEN MEETING ADJOURNED

NOTE: 15-MIN. BREAKS MAY BE GIVEN AT AN APPROPRIATE TIME DURING THE PROCEEDINGS